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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,327	05/30/2000	Michael T. Taylor	22660-0027US	1734

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EXAMINER
REDDING, DAVID A

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 07/15/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/584,327	TAYLOR ET AL.	
	Examiner	Art Unit	
	David A Redding	1744	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Cancellation of the non-elected claims 1-82 is acknowledged. Claims 83-85 are pending.

2. Applicant's arguments filed 4/30/03 have been fully considered but they are not persuasive.

Specification

3. The amendment filed 8/13/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claims 83 and 84, the claims define a "micro-sonicator" and "micro-fluidic system". The examiner has reviewed the specification and there is no support in the specification for such embodiments.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 83, and 84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 83 and 84, the claims define a "micro-sonicator" and "micro-fluidic system". The examiner has reviewed the specification and there is no support in the specification for such embodiments. A review of the specification reveals that there is no support in the specification for such an embodiment.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 83-85 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,100,084 (Miles et al.).

Claims 83-84 have priority only to the filing date (5/30/2000) of the instant application. Applicant asserts priority to provisional application 60/136,703, filing date 5/28/1999.

However, a review of the specification of the provisional document reveals that claims 83-85 are not supported by the disclosure within the provisional document. Actually, the provisional document is directed away from a "micro-sonicator" and designed to handle larger sample sizes (col.2, lines 21-col.3, line 26). Further, the provisional document does not disclose a membrane, rather specifies a gasket. Accordingly, the priority of claims 83-85 is the filing date of the instant application, which qualifies U.S. Patent 6,100,084 as prior art. As stated in applicants response filed 7/13/01, claims 1-14,17, and 18 correspond to claims 83-85, thus anticipating claims 83-85.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 84 and 85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/006,848 in view of USP 5,856,174. Claim 1 in the '848 application defines a device for lysing comprising, in part, a lysing chamber and an ultrasonic transducer which is coupled to the wall of the lysing chamber.

The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1). Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the '848 application, especially in view of the fact that both devices are used for lysing.

This is a provisional obviousness-type double patenting rejection.

10. Claims 84 and 85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 of copending Application No. 10/006,850 in view of USP 5,856,174 ('174). Claim 3 in the '850 application defines a device for lysing comprising, in part, a lysing chamber and an ultrasonic transducer which is coupled to the wall of the lysing chamber. The claim does not specify a transmission media. The '174 patent discloses a similar lysing chamber in which is added deionized water as a transmission media (example #1). Accordingly, it would be obvious to one skilled in the art to include the transmission media disclosed in the US patent into the device claimed in the '850 application, especially in view of the fact that both devices are used for lysing.

This is a provisional obviousness-type double patenting rejection.

11. Claims 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,168,948 B1 (Anderson et al.) in view of USP 5,856,174 ('174).

The Anderson et al. patent discloses an embodiment (figure 28) for controlling the degree of lyses.

The device comprises an injected molded chamber 3006 (cavity) which is covered by a polymeric base 3004, which is considered to be equivalent to the claimed membrane. The base may be in the form of adhesive tape or thin film (col.42, line 28-30). The device further comprises a piezoelectric crystal 3002 coupled to a thinned wall 3020 of the base 3004 via a filled balloon. In use, the piezoelectric crystal 3002 generates acoustic energy that is directed into the chamber to cause cells within the chamber to lyse (col.42, lines 4-30). In example #1 of the Lipshutz et al. patent water is used as an ultrasonic transmission media for lysing cells in a similar device to that disclosed in the Anderson et al. patent. Accordingly, it would have been obvious to one skilled in the art to use the transmission media disclosed in the Lipshutz et al. patent in the device (figure 28) described in the Anderson et al. patent in view the disclosed use of both devices for cell lysis using ultrasonic energy.

Response to Arguments

12. ***Applicants arguments concerning 35 U.S.C. 112 (1st paragraph) – New Matter***

Applicant asserts in pages 4 thru 5 of the response that both the provisional document and the specification of the instant application provides support for the term "micro-sonicator". The examiner disagrees. The support cited on pages 23,39 of the provisional document merely describes the **sonication** steps and nowhere is the term "micro-sonicator" used. Pages 7 and 34 the terms "microprocessors", "microcontrollers", are cited by applicant as support. Yet these terms describe the controls for the device and not the structure which performs the sonication step.

Alleged support in the specification cited by applicant for "micro-sonicator" is equally flawed. None of the citations expressedly or imply a "micro-sonicator". The support of page 28, lines 17-31 cited by applicant is directed to **reaction vessel** 40 not the chamber in the lysing chamber 86 in which ultrasound is used. The **reaction vessel** 40 is not a component of the lysing chamber 86. It is a separate element which makes of applicants "cartridge" invention. Applicant is directed to page 15, line 30 thru page 23, line 25. The evidence cited by applicant on page 104 of the provisional document is a general description of all of the chambers of the cartridge 20 with no specific reference to the lysing chamber 86 in which actual sonication of the sample occurs. The support cited on page 42 of the provisional document describing microliter volumes is directed to volumes contained in the **reaction chamber** 40 and not the lysing chamber.

Applicant' cited support for the term "microfluidic" is also found lacking. The support cited on page 5 of the provisional application is to an article by Anderson et al. and not a reference to applicant's claimed invention. Similarly, the support cited on page 9 of the instant specification describes fluidic systems, not micro-fluidic.

The support cited for the terms "ultrasonic transmission media" and "ultrasonic excitation of the transmission media" is persuasive. Specifically, page 6, lines 3-13 of the provisional document cited by applicant. Since the instant application, at the time of filing, incorporated by reference the contents of he provisional document, applicant has sufficient support for the terms "ultrasonic excitation of the transmission media". The rejection has been withdrawn.

Applicants arguments concerning the 35 U.S.C. 102 rejection

Applicant argues that the size of the lysing chamber in the instant application handles volumes smaller than the micro-sonicator in Miles et al. and inherently than has support for the added terms. The examiner disagrees. The chamber applicant is describing is the **reaction vessel** 40 and not the chamber in which sonication occurs, chamber 86. Accordingly, applicant does not have support for the terms "micro-sonicator" or "micro-fluidic" and does not receive benefit of the filing date of the provisional document . The effective date for the claims is the filing date of the instant application, 30 May 2000 , qualifying US patent 6,100,084 as prior art under 35 U.S.C. 102 (e).

Applicant's arguments concerning the Double Patenting rejections

The Terminal Disclaimers for US patents 6,440,725; 6,391,541; 6,431,476 are acknowledged and the rejections in view of those patents withdrawn. The provisional obvious-type double patenting rejections will remain until all other rejections of the claims are overcome.

The declaration filed on 4/30/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the US patent 6,100,084 reference. The evidence provided is illegible and therefore is not sufficient to show that applicant had reduced to practice the claimed invention prior to the filing date of USP 6,100,084.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 703-308-3910. The examiner can normally be reached on M,T,Th,Fr, 7:30-6:00pm.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

David A Redding
Primary Examiner
Art Unit 1744

D.A.R.
July 14, 2003